**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**
**CHARLESTON DIVISION**

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| **IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION**<br><br>**ETHICON WAVE 3 CASES LISTED IN EXHIBIT A OF DEFENSE NOTICE OF ADOPTION** | **Master File No. 2:12-MD-02327**<br>**MDL No. 2327**<br><br>**JOSEPH R. GOODWIN**<br>**U.S. DISTRICT JUDGE** |

**PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE OR LIMIT GENERAL-CAUSATION TESTIMONY OF DIONYSIOS K. VERONIKIS, M.D.**

COMES NOW, the Plaintiffs in the above-styled action, and file their Response in Opposition to Defendants Ethicon, Inc.'s and Johnson & Johnson's (hereinafter referred to as "Defendants") Motion to Exclude or Limit General-Causation Testimony of Dionysios K. Veronikis, M.D. (hereinafter referred to as "Dr. Veronikis"), and show the following:

**Argument and Citation of Authority**

I. Having already considered and ruled on Defendants' motion to exclude Dr. Veronikis, the only motion they were entitled to file under the controlling Docket Control Orders, the Court should deny this motion for reconsideration on its face.

This motion, and similar motions filed against other of Plaintiffs' general experts, epitomizes the unnecessary waste of effort and resources that this MDL generally – and the Docket Control Orders governing this wave process specifically – were intended to avoid and prevent. The fundamental purpose of this MDL is to foster efficiency and economy for the parties and for the court system through coordination. This wave process is intended to allow multiple cases to move forward in a coordinated manner under the auspices of this Court prior to remand for trial (or for trial in the MDL court where appropriate).

The Docket Control Orders governing the "wave" process are plainly intended to eliminate duplication and redundancy of effort, to conserve judicial and party resources, and to promote efficiency – especially with respect to the coordination of "general," or common, expert discovery. The DCO's expressly require the coordination of general experts, and specifically mandate that "[i]nsofar as multiple plaintiffs utilize the same general causation expert or experts, those experts shall be deposed only once on the issue of general causation." (PTO #192, PTO #206 and PTO #210, ¶ A.3(b)). The DCO's further provide that "[f]or the filing of *Daubert* motions on general causation issues only, the parties are instructed to file one *Daubert* motion per expert in the main MDL…. Each side may file one response and one reply in the main MDL to each *Daubert* motion." (*Id.*, ¶ B.2).[1] The requirements of the DCO's are abundantly clear: one deposition and one *Daubert* motion per general expert.

Consistent with the letter and spirit of the Court's orders, Plaintiffs identified several general experts applicable either to all wave cases, or else to all cases involving specific products. Dr. Veronikis was identified as a general expert with respect to the TVT and Gynemesh PS products. Pursuant to the Court's Docket Control Orders, Dr. Veronikis was deposed only one time with respect to his general opinions, and the Defendants filed their one allowed *Daubert* motion challenging those general opinions. (Dkt. No. 2270). Plaintiffs generally responded to the Defendants' *Daubert* motion (Dkt. No. 2284), and the Defendants filed their reply. (Dkt. No. 2313). In Wave 2, the Defendants adopted their prior *Daubert* motion relative to Dr. Veronikis and incorporated that motion by reference. (Dkt. No. 2444). The Wave 2 Plaintiffs likewise generally adopted their Response. (Dkt. No. 2580).

[1] While the DCO's refer to "general causation," the orders are intended to apply to all "general" experts, i.e., experts who intend to offer opinions relative to the plaintiffs generally or relative to all plaintiffs implanted with a certain product; that is certainly how the parties have treated those orders throughout this wave process.

The Court ruled on the Defendants' *Daubert* motion against Dr. Veronikis (Dkt. No. 2712), along with Defendants' other *Daubert* motions filed against Plaintiffs' general experts.

Apparently dissatisfied with the Court's ruling (not only with respect to Dr. Veronikis, but several other general experts, as well), the Defendants are essentially asking the Court for a do-over. Although presented as a "supplemental motion," the present motion improperly seeks reconsideration of the Court's *Daubert* ruling with respect to this witness. Dr. Veronikis has not offered any new opinions. He has not provided any additional or supplemental expert report or information. Dr. Veronikis has not been re-deposed on his general opinions. There is simply nothing "new" about Dr. Veronikis's general opinions or testimony.

Moreover, there is nothing new about the Defendants' argument here. Defendants urge six separate "bullet point" bases, which serve as their argument headings in their brief, for why they believe Dr. Veronikis's opinions should be excluded.[2] This list is nearly verbatim of the "bullet points" and headings in Defendants' *Daubert* motion filed with respect to Veronikis – *more than four months ago*.[3] Plaintiffs have responded to each of these arguments. The Court ruled on each of the Defendants' specific challenges to Dr. Veronikis, or else reserved ruling on those issues for trial. (Dkt. No. 2712). Defendants apparently disagree with how the Court ruled

[2] "Opinions relating to what should be included in an IFU."; "Opinion that TVT mesh is not suitable for implantation because it degrades, frays, and loses particles."; "Opinion that TVT is defective because the surgical technique used is unsafe."; "Opinion that all mesh is unsafe for vaginal use."; "Opinion that Pronova is a safer alternative to Gynemesh PS."; "Opinions that are legal conclusions or relate to Ethicon's motive, knowledge, and intent." (Dkt. No. 2821, pp. 1-2).

[3] "Opinion as to what an adequate IFU should have contained."; "Opinion that TVT mesh is not suitable for its intended application because it degrades, frays, and experiences particle loss."; "Opinion that TVT mesh is defectively designed because Ethicon's recommended surgical technique is unsafe."; "Opinion that all mesh is unsafe for vaginal use"; "Opinion that Pronova is a safer alternative to Gynemesh PS."; "Opinions that Ethicon failed to adequately warn physicians that TVT and Gynemesh PS are defectively designed because they are not reasonably safe for their intended uses."; "Opinions relating to Ethicon's motive, knowledge and intent." (Dkt. No. 2271, pp. 1-2).

with respect to their *Daubert* motion against this witness, and they want a second bite at the apple.

In *In re C.R. Bard, Inc.*, 948 F.Supp.2d 589, 649 (S.D.W.Va.2013), the Court recited the legal standard for a motion for reconsideration, stating:

> "[I]t is improper to file a motion for reconsideration simply to ask the Court to rethink what the Court had already thought through—rightly or wrongly." *Mt. Hawley Ins. Co. v. Felman Production, Inc.*, No. 3:09–cv–00481, 2010 WL 1404107, at *2 (S.D.W.Va. Mar. 30, 2010)….
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> [A]lthough a "motion for reconsideration under Rule 54(b) is not subject to the strictures of a Rule 60(b) motion," this district has been "guided by the general principles of Rules 59(e) and 60(b)" in determining whether a Rule 54(b) motion should be granted. *Shrewsbury v. Cyprus Kanawha Corp.*, 183 F.R.D. 492, 493 (S.D.W.Va.1998). The Fourth Circuit has recognized three grounds for amending a judgment: "(1) to accommodate an intervening change in controlling law; (2) to account for new evidence not available at trial; or (3) to correct a clear error of law or prevent manifest injustice." *Pac. Ins. Co. v. Am. Nat. Fire Ins. Co.*,148 F.3d 396, 403 (4th Cir.1998). Such motions "may not be used, however, to raise arguments which could have been raised prior to the issuance of the judgment, nor may they be used to argue a case under a novel legal theory that the party had the ability to address in the first instance." *Id.* Finally, "reconsideration of a judgment after its entry is an extraordinary remedy which should be used sparingly." *Id.* (quoting 11 Wright et al., Federal Practice and Procedure § 2810.1, at 124 (2d ed. 1995)).

Defendants cannot properly ask the Court to rethink what has already been thoroughly argued, briefed and decided. Likewise, to the extent they claim to raise "new" arguments, Defendants cannot properly seek to assert arguments that could have been raised before, or present a new theory or defense that they had the ability to raise in their initial motion, but chose not to.[4] Both parties, and the Court and its staff, have already devoted substantial time and

[4] The fact that Defendants did not seek to raise any "new" arguments with respect to this expert in their Wave 2 briefing, but instead adopted and incorporated their prior motion from Wave 1 (consistent with the letter and spirit of the Court's Docket Control Orders), is telling. Only after the Court ruled upon their motion did Defendants seek to raise what they inaccurately claim are "new" arguments (they are not). This further serves to demonstrate that this motion is merely an attempt to have the Court reconsider what it has already ruled upon. Even if they do raise any new arguments, however, the same result is warranted: the motion should be denied.

resources to these same issues, and they have been authoritatively decided. Respectfully, this "supplemental" motion is an unwarranted waste of time, effort and resources, and it should be denied.

II. If the Court were to consider the merits of this improper motion for reconsideration, the Court should allow Dr. Veronikis (and every physician expert named by the wave Plaintiffs) to opine on the risks posed by the Defendants' product at issue and whether the product's IFU adequately conveyed those risks, which is consistent with this Court's consistent ruling and consistent with applicable case law considering the same issue.

To the extent the Court were inclined to consider the Defendants' improper arguments on their merits, however, Plaintiffs wish to address the Defendants' contention that Dr. Veronikis somehow lacks so-called "additional expertise" to offer an opinion regarding what should be include in an IFU. (Dkt. No. 2821, pp. 2-3). A qualified and experienced urogynecologist is not required to have so-called "additional expertise" regarding warnings to offer an opinion regarding the effects a proper warning would have had on a physician. As Defendants have repeatedly pointed out, these products are sold only to physicians and used only by physicians. Therefore, the adequacy of a warning can only properly be judged by a physician's opinion. A so-called "warnings expert" cannot offer an opinion regarding the adequacy of the Defendants' IFU because they lack the requisite knowledge, experience, training and expertise regarding the risks posed by the products and whether the IFU properly conveyed those risks to physicians. Not only should a physician be allowed to testify as to the adequacy of a warning intended for a physician, *only* a physician can offer such testimony.

Prior to the Court's rulings in the Ethicon wave cases, the Court has consistently held that qualified physicians can opine regarding whether the risks associated with a product are adequately conveyed in the product's IFU, despite the physician's alleged lack of "additional expertise" regarding product labeling. Indeed, in the sole case cited in support of this

exclusionary ruling in these wave cases, *Wise v. C.R. Bard, Inc.*, 2015 WL 521202, *14 (S.D.W.Va. 2015), the Court held as follows:

> Dr. Raybon has no demonstrated experience in the requirements for product labeling, and as such, he may not testify as to what the Avaulta label should or should not have included under the law. However, as an experienced urogynecologist, he may testify about the risks he perceives that the Avaulta poses to patients and then opine that the Avaulta IFU did not convey those risks. *See In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, 2011 WL 6301625, at *11 (S.D.Ill.Dec. 16, 2011) ("[D]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings ...." (internal quotations and brackets omitted)). To the extent that Dr. Raybon's opinions fit within this comparison, they are not excluded at this time, and Bard's motion on this issue is **DENIED.**

Consistent with several prior rulings on this specific issue throughout this litigation, an expert urogynecologist, like Dr. Veronikis – and every one of the general physician experts proffered by the Plaintiffs in these wave cases – is qualified to and should be allowed to opine "about the risks he perceives that the [product] poses to patients and then opine that the [product's] IFU did not convey those risks." *See also*, *Edwards v. Ethicon, Inc.*, 2014 WL 3361923 at *13 (2:12-cv-01378 [Dkt. 139] S.D.W.V. July 8, 2014) ("Dr. Blaivas [an expert urogynecologist] need not be an expert on product warnings per se. Rather, as a urologist, Dr. Blaivas is qualified to testify about the risks of implanting the TVT-O and whether those risk were adequately expressed on the TVT-O's IFU."); *Tyree v. Boston Scientific Corp.*, 2:12-cv-08633 10/17/14 Memorandum Opinion and Order (Daubert Motions), Doc. 444 at p. 77, *quoting Huskey v. Ethicon, Inc.*, 2014 WL 3362264 at *5 (2:12-cv-05201 [Dkt. 271] S.D.W.V. July 8, 2014) ("[A]s a urologist, Dr. Blaivas is qualified to testify about the risks of implanting the TVT-O and whether those risks were adequately expressed on the TVT-O's IFU. Dr. Blaivas is qualified to render an opinion as to the completeness and accuracy of Ethicon's warnings and—'it follows from that—the extent to which any inaccuracies or omissions could either deprive a

reader or mislead a reader of what the risks and benefits' of the TVT-O was when the warnings were published.").

Other courts that have considered the same issue have reached the same conclusion, which is the logically sound and legally correct result. In *In re Yasmin and Yaz (Drospirenone) Prods. Liab. Litig.*, 2011 WL 6301625, *11-*13 (S.D.Ill.2011), which the Court cited in *Wise*, *supra*, the drug manufacturer argued that the plaintiffs' proffered experts, both Obstetrician-Gynecologists, were not qualified to offer opinions regarding the adequacy of its labeling, and further that their opinions were not based on any reliable methodology. The Court rejected its argument, and held instructively as to one of the OB-GYN experts as follows:

> As a practicing OB/GYN tasked with making prescription decisions on a daily basis, Dr. Bercy-Roberson is qualified to opine as to how certain knowledge, obtained through studies, reports, and internal Bayer documents, would have affected her previous prescription-related decisions. Dr. Bercy-Roberson does not require expertise in FDA regulations to opine in this manner, as she does not comment on the conduct of the FDA. Further, doctors are 'fully qualified to opine on the medical facts and science regarding the risks and benefits of [drugs]…and to compare that knowledge with what was provided in the text of labeling and warnings for FDA approved drugs.' *In re Diet Drugs Prods. Liab. Litig.*, MDL 1203, 2000 WL 876900, *11 (E.D.Pa. June 20, 2000). Thus, Dr. Bercy-Roberson is qualfied to render an opinion as to the drug label's completeness and accurateness. *See id*....
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> Thus, as Dr. Bercy-Roberson's opinion based on peer-reviewed sources and data, her methodology is sound. The correctness of her opinion is left to the trier of fact's determination.[5]

*See also Smith v. Wyeth-Ayerst Laboratories Co.*, 278 F.Supp.2d 684, 702 (W.D.N.C. 2003) (citing *In re: Diet* Drug MDL PTO 1332, where the MDL court concluded physicians are "'qualified to render an opinion as to the labels' completeness, accuracy, and . . . the extent to which any inaccuracies or omissions could either deprive a reader or mislead a reader of what the

[5] The same holding with respect to the Plaintiffs other proffered OB-GYN expert in the *Yaz* MDL (Anthony Disciullo) – based on his extensive clinical experience and review of peer-reviewed literature and company documents, he was qualified to offer opinions as to the adequacy of the drug warning label, and his opinions were reliable.

risks and benefits . . . are or were at the time the labeling was published.'…"); *Accord, Burton v. Wyeth-Ayerst Labs. Div. of Amer. Home Prods. Corp.*, 513 F.Supp.2d 708, 712 (N.D.Tex.2007); *In re Rezulin Prods. Liab. Litig.*, 309 F.Supp.2d 531, 556 (S.D.N.Y.2004) ("Pursuant to the defendants' concession [in light of *In re: Diet Drugs*], and subject to relevance rulings to be made by the trial courts, these [physician expert] witnesses are not precluded from offering otherwise admissible testimony as to the accuracy of the Rezulin label."); *In re Baycol Prods. Litig.*, 532 F.Supp.2d 1029, 1063-64 (D.Minn.2007) (citing *In re: Diet Drugs* opinion in denying defense *Daubert* motion to exclude physician expert opinion regarding drug labeling, stating "The Court agrees that [the plaintiffs' physician expert] is qualified to render an opinion regarding the completeness or accuracy of the Baycol label based on his knowledge of the risks of Baycol and his own clinical experience."). This legally correct standard, which the Court has routinely applied in this litigation, should continue to be applied going forward.

III. Contrary to Defendants' inaccurate assertion, Dr. Veronikis' testimony establishes that he does possess "additional expertise" regarding product labeling, having himself developed commercialized surgical devices, and prepared the warnings relative to those devices.

To the extent that the Court intends to apply the "additional expertise" standard, which Plaintiffs submit is an improper standard and is contrary to the Court's prior rulings and the consensus of applicable case law, then Plaintiffs should be given full opportunity to address their experts' testimony and qualifications regarding warnings at trial. For example, while Defendants urge that Dr. Veronikis has no "additional expertise" relating to product labeling, his testimony demonstrates to the contrary. Dr. Veronikis testified that he has written "several" IFUs for commercialized surgical instruments that he designed himself, which includes both the surgical technique and the product he designed. (Veronikis 4/30/16 depo., 163:15-165:13). These instruments, which Dr. Veronikis designed and for which he wrote the IFU, include a vaginal

dilator for women with shortened vaginas, and a surgical device used in performing sacrospinous colpopexy. (*Id.*). Although Defendants attempt to downplay this testimony, it remains a fact that Dr. Veronikis' testimony directly disproves any contention that he has no "additional expertise" in product labeling. Even under the inappropriate "additional expertise" standard urged by the defense, Dr. Veronikis is qualified to opine as to the adequacy of the Defendants' IFUs for the Gynemesh PS and TVT, and he certainly is qualified – as are all of Plaintiffs' physician experts – to offer his expert opinion as to the risks of the Defendants' pelvic mesh devices and whether the IFUs adequately warn doctors (like themselves) about those risks. Defendants' motion, to the extent it is considered at all, should be denied.

**Conclusion**

The governing DCO's allow only one deposition (by one designated attorney) and one *Daubert* motion per general expert. The intent of that express limitation is clear: to avoid the unnecessary duplication of effort, and consequent waste of time and resources, inherent in re-deposing and re-arguing over the same opinions from the same expert. The Court has ruled on Defendants' one *Daubert* motion with respect to Dr. Veronikis. Defendants cannot seek to have the Court reconsider that ruling, and it cannot seek to assert allegedly "new" arguments that it could have but did not raise in its motion. Defendants' motion should be denied.

If the Court were to consider Defendants' improper arguments on their merits, however, the alleged "additional expertise" standard is invalid and inconsistent with the Court's consistent rulings and applicable case law, and in any event, Dr. Veronikis has demonstrated "additional expertise" in product labeling having designed his own surgical devices and prepared the IFU's for those products.

Dated: October 7, 2016

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on October 7, 2016, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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